K052919

510(k) Summary of Safety and Effectiveness

JAN 13 2006

General Information

Classification Class II

Trade Name Microsulis Tissue Ablation (MTA) System is comprised of:

- MTA Sulis™ V Generator
- Applicator and Temperature probes

Submitter Microsulis Americas, Inc.
275 Wyman Street, Suite 12
Waltham, MA 02451
1 -781- 547- 7710

Contact Timothy Y Cowart
Executive Vice President, Chief Regulatory Officer

Intended Use

The Microsulis Tissue Ablation (MTA) System and accessories are for use in the intraoperative coagulation of soft tissue.

Predicate Devices

- Tyco/Radionics Cool-Tip™ RF System K984552
- Vivant Medical VivaWave™ Microwave System K011676
- Vivant VivaTherm™ Temperature Measurement System K031556
- Vivant VivaTip Microwave Ablation Probe and Accessories K032702

Device Description

The MTA surgical applicator is inserted into soft tissue and coagulates a volume of tissue surrounding the active area of the applicator tip. Temperature probes are included in the applicator kits to determine the temperature at the periphery of the coagulated tissue or near vital structures. The applicator is to be used with the MTA Sulis™ V microwave generator which is manually set at the desired power levels by the operator.

Materials

All patient contact materials used in the manufacture of the MTA System are suitable for this use and have been used in numerous previously cleared products.

Performance Data

Performance testing was undertaken to ensure that the MTA System functions as intended and meets design specifications. Sufficient data were obtained to demonstrate that the device is substantially equivalent to the aforementioned predicate devices and meets safety and effectiveness criteria. In addition, the testing demonstrates that the MTA System complies with the following standards:

- Electrical Safety - UL 60601-1:2003 Medical Electrical Equipment. Part 1: General requirements for safety.
- Electromagnetic compatibility – Meets EN 60601-1-2, EN55011, & IEC60601-1-2:2001
- Biocompatibility - ISO 10993, Biological Evaluation of Medical Devices
- Sterility - Sterilization validation requirements of EN550 and ISO 11135
- Shelf Life - Distribution Simulation per ASTM D4169, Seal Strength Evaluation per ASTM F88
- Packaging – International Safe Transit Association (ISTA) Procedure 2A 2004, Package Distribution Simulation per ASTM D4169

Summary of Substantial Equivalence

The MTA System is equivalent to the predicate products. The indications for use, basic overall function, methods for manufacturing, and materials used are substantially equivalent. Microsulis believes that the MTA system is substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2006

Mr. Timothy Y. Cowart, Esq., P.E.
Executive Vice President of Regulatory Affairs
Chief Regulatory Officer
Microsulis Americas, Inc.
275 Wyman Street, Ste. 12
Waltham, Massachusetts 02451

Re: K052919
Trade/Device Name: Microsulis Tissue Ablation (MTA) System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: NEY
Dated: December 12, 2005
Received: December 14, 2005

Dear Mr. Cowart:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

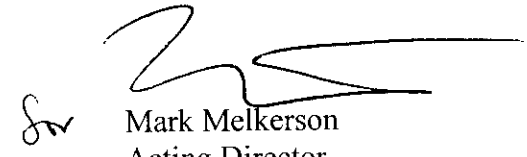
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other

Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



for Mark Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K052919

Indications for Use

510(k) Number (if known): K052919

Device Name: Microsulis Tissue Ablation System and Accessories

Indications For Use:

The Microsulis Tissue Ablation (MTA) System is indicated for the intraoperative coagulation of soft tissue.

Prescription Use yes AND/OR Over-The-Counter Use No
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K052919